

Remarks

Claims 1-8 and 12 are pending in the application. Claims 1-8 and 12 have been amended. Claim 1 is amended to address the rejection under 35 U.S.C. § 112, second paragraph, as outlined below. Claims 1-8 and 12 are further amended to put the claims in a conventional U.S. format. No new matter has been added by way of these claim amendments and the scope of the claims is not altered by these claim amendments.

Section 112, second paragraph

Claims 1 is rejected under 35 U.S.C. § 112, second paragraph, because the claim is deemed to not recite the steps of the process in a clear fashion. Claim 1 is amended to recite the steps of the process in subparagraphs. Applicants submit that claim 1, as amended, meets the requirements of 35 U.S.C. § 112, second paragraph.

Section 102(b)

Claims 1-8 and 12 are rejected under 35 U.S.C. § 102(b) as being anticipated by Jenkins (EP 0 205 282 and US 4,940,587). Since the specifications for EP 0 205 282 and US 4,940,587 appear to be nearly identical and are based on the same priority document, Applicants will address both references simultaneously.

The Jenkins patents describe a pharmaceutical preparation that adheres to the oral or nasal mucosa, for parenteral administration of a drug over an extended period of time. The preparation contains a matrix of a higher aliphatic alcohol at 5-35% w/w and a hydroxyalkylcellulose of a numerical average molecular weight above 200,000 at 2-15% w/w, in which is dispersed a pharmaceutical. This mixture is hydrated by addition of a quantity of water between 1 and 5 times the dry weight of the cellulose, partially dried, granulated and coated with a hydroxyalkylcellulose and formed into a tablet or capsule. The coating helps the tablet or capsule adhere to the oral mucosa while drug is slowly released through the mucosa to the patient.

In contrast, the invention of the instant application relates to an orally administrable pharmaceutical preparation comprising 40-95% w/w hydroxypropylcellulose of 250,000 to 1,200,000 average molecular weight and a pharmaceutical. This mixture is granulated to particles of 0.2 to 3.0 mm size.

Jenkins therefore does not describe a pharmaceutical preparation containing 40-95% w/w of hydroxypropylcellulose, as claimed in the instant application. Jenkins only describes a preparation containing 2-15% w/w of a hydroxyalkylcellulose. Likewise, none of the examples in Jenkins describes a formulation containing greater than 12.5% hydroxypropylcellulose. Since the cited references do not contain all of the elements of the claims, the claims are allowable under 35 U.S.C. § 102(b).

#### Section 103(a)

Claims 1-8 and 12 are rejected under 35 U.S.C. § 103(a) as being obvious in light of Jenkins (EP 0 205 282) or Jenkins (US 4,940,587). First, as described above, Jenkins does not teach or suggest a pharmaceutical preparation containing 40-95% w/w hydroxypropylcellulose. Also, Jenkins does not teach or suggest formation of a mixture of 40-95% w/w hydroxypropylcellulose and a pharmaceutical into granules having 0.2-3.0 mm. Furthermore, Jenkins does not teach or suggest administration of said pharmaceutical preparation as a multiple-unit preparation.

Jenkins cites the term 'oral', but it is clear from the specification that the preparations according to Jenkins are not to be swallowed (column 1, paragraph 3). On the contrary, the gist of Jenkins is to avoid swallowing of the preparation. The Jenkins preparations are to be applied buccally or nasally, that is remaining in the oral or nasal cavity, resulting in parenteral administration. In contrast, the preparations according to the present invention are to be administered orally.

- Finally, Jenkins does not teach or suggest the use of said preparation for a food-effect independent method of orally administering the pharmaceutical.

Since the cited references do not teach or suggest the elements of the claims, the claims are allowable under 35 U.S.C. § 103(a).

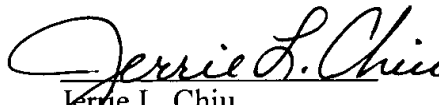
Conclusion

Applicants respectfully submit that the pending claims are in condition for allowance. Reconsideration is respectfully requested. Please charge any fees due with this amendment to deposit account number 13-3372. If the Examiner believes that a conversation with Applicants' attorney would be helpful in expediting prosecution of this application, the Examiner is invited to call the undersigned attorney at (203) 812-3964.

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